NEWS RELEASE
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ATTORNEY GENERAL RAVNSBORG ANNOUNCES $116.9 MILLION MULTISTATE SETTLEMENT WITH JOHNSON & JOHNSON, ETHICON, INC.

PIERRE, S.D. – Attorney General Jason Ravnsborg today announced a multistate settlement along with 41 states and the District of Columbia which will require Johnson & Johnson and its subsidiary Ethicon, Inc. to pay nearly $116.9 million for their deceptive marketing of transvaginal surgical mesh devices.

A multistate investigation found the companies violated state consumer protection laws by misrepresenting the safety and effectiveness of the devices and failing to sufficiently disclose risks associated with their use. South Dakota will receive $1,423,549.52 under the settlement.

"I hope this case serves as a warning that our office remains vigilant in seeking to defend South Dakota consumers," said Ravnsborg. "When consumers, especially those dealing with health care, are making their decisions they need to know they are being told the truth so they can be better informed and equipped to make a good decision for their, and their families, well-being."

Transvaginal surgical mesh is a synthetic material that is surgically implanted through the vagina to support the pelvic organs of women who suffer from stress urinary incontinence or pelvic organ prolapse.

The multistate investigation found the companies misrepresented or failed to adequately disclose the products' possible side effects, including the risk of chronic pain and inflammation, mesh erosion through the vagina, incontinence developing after surgery, painful sexual relations, and vaginal scarring. Evidence shows the companies were aware of the possibility for serious medical complications but did not provide sufficient warnings to consumers or surgeons who implanted the devices.

Under the settlement, Johnson & Johnson has agreed to pay $116.86 million to the 41 participating states and District of Columbia. The settlement also provides injunctive relief, requiring full disclosure of the device's risks and accurate information on promotional material, in addition to the product's "information for use" package inserts.

Among the specific requirements, the companies must:

- Refrain from referring to the mesh as "FDA approved" when that is not the case
- Refrain from representing in promotions that risks associated with mesh can be eliminated with surgical experience or technique alone
- Ensure that product training provided to medical professionals covers the risks associated with the mesh

- Omit claims that surgical mesh stretches after implantation, that it remains soft after implantation, that foreign body reactions are transient and that foreign body reactions "may" occur (when in fact they will occur)
- Disclose that mesh risks include: fistula formation, inflammation, as well as mesh extrusion, exposure and erosion into the vagina and other organs
- Disclose risks of tissue contraction, pain with intercourse, loss of sexual function, urge incontinence, de novo incontinence, infection following transvaginal implantation and vaginal scarring
- Disclose that risks include that revision surgeries may be necessary to treat complications, that revision surgeries may not resolve complications and that revision surgeries are also associated with a risk of adverse reactions

Joining South Dakota in this multistate settlement are Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, and Wisconsin.

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